ARGUMENTS/REMARKS

Claims 28 through 37, 39 through 46, and 53 through 57 are currently pending in the present application. Claims 28, 41 and 53 are independent. Claims 28, 32, 33, 34, 40, 41, 42, 43, 45, 46 and 53 through 56 are amended. Claim 57 is new. Claims 38, 47 through 52 are canceled.

In response to Examiner's comments regarding and PCT/IL03/00599 filed on July 22, 2003 and Provisional Application Serial No. 60/397,042 filed on July 22, 2002 priority under 35 U.S.C. 119(e), applicant notes that a corrected oath was filed on June 23, 2008 properly claiming priority. This corrected Oath was filed in response to paragraph the objection on page 2 of the office action mailed on February 22, 2008. Further, the Examiner in the present application indicated that the acknowledgment of priority has been made in the Office Action Summary Sheet mailed in October 17, 2008. Further, Applicants are aware that priority to the provisional application filing date will only be had by subject matter in the present application that satisfied 35 U.S.C. 112, first paragraph from the provisional application.

In the office action, the drawings were objected to for failing to show the at least one sensor specified in the claims. In response, Figs. 2, 5B and 7D were amended in the attached Replacement Sheets 2, 5 and 8, to include as a sensor a sensor, designated by numeral 19. Corresponding amendments in the specification are requested as set forth on page 3 of this letter.

In the office action, claims 28-56 were objected to for a number of informalities raised in connection with claims 28, 32-33, 41, 42-43, 47, 51, 53 and 54-55. In response claims 28, 32, 33, 41, 42, 43, 53, 54 and 55 have now been corrected to remove the inconsistencies indicated by the Examiner. Applicant respectfully requests that the objections raised in connection with these claims be withdrawn.

The objections raised in connection to claims 47 and 51 have been rendered moot in view of the cancellation of those claims.

In the office action, claims 28-40 were rejected under 35 USC §112, second paragraph, as being indefinite for reciting a broad range together with narrower range. In response claim 28 has been amended to recite that the system is for "administrating a regulated flow of air to a person suffering from sleep apnea".

In the office action, claims 28, 41 and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/565,363. U.S. This rejection is rendered moot because with respect to claim 47 that has been canceled by the present amendment. Any terminal disclaimer that may be required will be considered after allowance of the pending claims over the prior art of record. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 28-29, 33-36, 41, 43-44, 47-48 and 53 were rejected under U.S.C. § 103(a) as being unpatentable over Moa et al. (5,193,532) in view of Boussignac (US 6,363,935). The rejections with respect to claims 47 through 48 are hereby rendered moot, as those claims have been canceled.

Independent claim 28 is directed to a portable respiratory aid system for administrating a regulated flow of air to person suffering from sleep apnea. Claim 28 provides for a source of high pressure air; an air delivery nasal interface having two air delivery units configured for delivering a flow of air each to a respective nostril of the person. The two air delivery units are pivotally mounted on opposite ends of a flat elongated flexible member configured to be placed above the upper lip of said person. Each of the two air delivery units has a Venturi device having a hollow member defining a central space and an inlet which opens into the central space, a first open end that opens to surrounding ambient air and a second open end that is

provided with a nasal adaptor attachable to a nostril of the person. The inlet is configured for receiving a flow of high pressure air via a thin flexible tubing and for directing said flow of high pressure air toward said second open end. The system further provides for a thin flexible tubing bifurcating into two branches for delivering a flow of high pressure air from the source of high pressure air to the inlet of each Venturi device. The tubing configured for serving as strapping means for strapping the air delivery nasal interface to said person's head. The system further including at least one sensor for monitoring breathing of the person and a control unit operably connected to the at least one sensor for regulating the flow of high pressure air in accordance with the monitored breathing. The control unit including a microprocessor and a memory device configured for monitoring a breathing pattern over time, thereby enabling a real-time regulation of the flow of air in accordance with respiratory cycles of the person and a long term regulation in accordance with the monitored breathing pattern.

Independent claim 28 has now been amended by incorporating the limitations of previous claims 38 and 51 reformulated to enhance clarity, and further to include the limitation that the thin tubing serving for delivering the high pressure air to the nasal interface bifurcates into two branches that serve as strapping means for strapping the nasal interface to the head of the person. Support for the bifurcating tubing and its use for strapping the nasal interface to the person's head can be found on paragraph [0055] and in Figs. 6. Support for the elongated member, on which the two air delivery units are mounted, can be found in Fig. 6A.

Independent claim 41 is directed to an air delivery nasal interface including two air delivery units for delivering a flow of air, each to one of a pair of nostrils of a person. The two air delivery units are pivotally mounted on opposite ends of a flat elongated flexible member configured to be placed above the upper lip of the person. Each of the two air delivery units includes a Venturi device having a hollow chamber defining a central space and an inlet which opens into the central space. The hollow member has a first open end which opens to surrounding ambient air and a second open end provided

with a nasal adaptor. The inlet of each Venturi devices is configured to receive a flow of high pressure air via a thin tubing and to direct the flow toward the second open end. The flow of high pressure air upon entering the central space acts as a driving force for drawing ambient air through the first end toward the second open end. Claim 41 further provides for a thin flexible tubing bifurcating into two branches for connecting a source of high pressure air to each of said inlets of said two air delivery units. The tubing is configured for serving as strapping means for strapping the air delivery nasal interface to a person's head. The system also includes at least one sensor for monitoring breathing of a person using the air delivery nasal interface unit.

Independent claim 41 has now been amended to include the limitations of previous claim 51 reformulated to enhance clarity, and further to include the limitation that the thin tubing connecting between the source of pressure air and the nasal interface bifurcates into two branches that serve as strapping means for strapping the nasal interface to the head of the person. Support for the bifurcating tubing and its use for strapping the nasal interface to the person's head can be found on paragraph [0055] and in Figs. 6. Support for the elongated member on which the two air delivery units are mounted can be clearly seen in Fig. 6A.

Claim 53 provides for connecting a portable source of high pressure air by means of a thin tubing to an air delivery nasal interface wherein the air delivery nasal interface comprises two Venturi devices. Each of the Venturi devices has a hollow member defining a central space and an inlet that opens in to the central space. Each hollow member has a first open end that opens into surrounding ambient air and a second open end provided with a nasal adaptor attachable to a person's nostril. Each of the Venturi devices is configured to receive a flow of high pressure air through the inlet and to direct the flow of high pressure air toward the second end, thereby drawing ambient air from the first open end toward the second open end and reducing the high pressure to a pressure of lower value. The method further includes monitoring the breathing of the person by means of a sensor; and delivering a flow of high pressure air from the source

of high pressure air via the thin tubing to the air delivery nasal interface via the inlets of the two Venturi devices. Claim 53 further provides for automatically regulating the flow of high pressure air in accordance with the monitored breathing so as to administer a flow of a desired pressure to said person when an apneic breathing pattern is detected and turning off the flow of high pressure air upon detection of a regular non-obstructed breathing. Independent claim 53 is directed to a method for administrating a controlled flow of air to a person suffering from sleep apnea, in accordance with the real-time needs of the person.

Independent claim 53 (for method) has now been amended to recite that the regulation of the high pressure flow is performed automatically so as to administer a flow of a desired pressure to said person when an apneic breathing pattern is detected and turning off the flow of high pressure air upon detection of a regular non-breathing.

The Moa et al. patent teaches an air delivery nasal interface for delivering a constant stream of air/respiratory gas to a patient with impaired pulmonary function, the main purpose of which is to supply air at a constant pressure throughout the breathing cycle (col. 1, lines 28 – 31 and lines 36 – 40). Thus, the Moa et al. patent does not teach a sensor for monitoring breathing for allowing self-regulation of the air supply according to the requirements of the patient.

The Boussignac patent is directed to a device for respiratory assistance having a single tube and a valve that is controlled by a sensor. The sensor detects the patient's exhalation and adjusts the valve to be closed during exhalation. Thus, the valve is opened and closed alternately in response to the breathing cycle and cannot respond to changes in user needs as does the present invention.

Neither Moa et al. nor Boussignac disclose two Venturi devices each having a respective inlet, or that the tubing connecting between the source of high pressure air and

the two inlets of the Venturi devices serves as the strapping means for strapping the nasal interface to the person's head for holding the nasal interface in place. Further, neither patent discloses two independent Venturi devices that are mounted on opposite ends of a flat elongated flexible member configured to be placed above the upper lip of a person. Further with regard to independent claim 28, neither Moa nor Boussignac disclose a controller unit having a microprocessor and a memory device which in conjunction with a sensor allows for short term and long term regulation of the air flow delivered to the person in accordance with real-time respiratory cycles and the long term breathing pattern of the person.

Applicants sincerely request the withdrawal and the 35 U.S.C. 103(a) rejection with regard to independent claims 28, 41 and 53 and the dependent claims 29, 33-36, 43-44, 47 and 48, respectively, that depend therefrom.

Claim 30, 40, 45-46, 50 and 54 were rejected under U.S.C. § 103(a) as being unpatentable over Moa et al. in view of Boussignac and further in view of Sherrod ((5,979,444). Claim 50 was canceled and any rejection directed to that claim is rendered moot.

The Sherrod patent is directed to a device for providing oxygen to a non-breathing person as part of a cardiopulmonary resuscitation (CPR) which provides for evacuating air during exhalation phase. The device includes a face mask to be placed over the mouth of the patient, an oxygen dispenser and a conveying piece which alternately injects oxygen into the mask during inhalation phase and withdraws air from the patient's mouth during exhalation phase.

Thus, Sherrod differs from pending claims 28 and 41 in both structure and function. First, Sherrod does not teach a small nasal interface having two independent Venturi devices that are pivotally mounted on opposite ends of a flat member, but rather, a face mask. Second, Sherrod does not teach the device to include a sensor for

monitoring the patient's breathing, nor a control unit having a microprocessor and a memory device for monitoring the breathing pattern over time, as claimed. Further, according to Sherrod, the high pressurized gas delivered to the respiratory interface is oxygen, not air as in the present system. As such, the Sherrod patent does not remedy the defects of either the Moa et al. patent or the Boussignac patent.

Reconsideration and withdrawal of the 35 U.S.C. 103(a) rejections with respect to claims 30, 40, 45-46, 50 and 54 are respectfully requested.

Claims 31 and 37 were rejected under U.S.C. § 103(a) as being unpatentable over Moa et al. in view of Boussignac and further in view of Hill et al. (US 2002/0096174).

The Hill et al. publication is offered for the purpose of teaching a portable oxygen concentrator system wherein the compressor is preferably an oil-less compressor to prevent the possibility of oil or grease from entering the air flow path.

However, Hill et al. does not remedy the deficiencies of either the Moa et al. patent or Boussignac. Hill does not disclose a two independent Venturi devices each having a respective inlet, or that the tubing connecting between the source of high pressure air and the two inlets of the Venturi devices serves as the strapping means for strapping the nasal interface to the person's head for holding the nasal interface in place. Further, Hill et al. does not discloses two independent Venturi devices that are mounted on opposite ends of a flat elongated flexible member configured to be placed above the upper lip of a person. Finally, Hill et al. does not disclose a controller unit having a microprocessor and a memory device which in conjunction with a sensor allows for short term and long term regulation of the air flow delivered to the person in accordance with real-time respiratory cycles and the long term breathing pattern on the person.

Claims 49, 51 and 52 were rejected under U.S.C. § 103(a) as being unpatentable over over Moa et al. in view of Boussignac and further in view of Goldstein (5,752,510).

Claims 47 through 52 have been canceled by the present amendment. Accordingly, the rejections with regard to these claims are hereby rendered moot.

Claims 32, 38 and 42 were rejected under U.S.C. § 103(a) as being unpatentable over Moa et al. in view of Boussignac and further in view of Miles (5,353,788).

The Miles patent is directed to a system and method for controlling and monitoring externally administered breathing air pressure in a series of cycles. For the treatment of sleep apnea, the Miles patent discloses passing an airflow at elevated pressure into the nasal passages through a nasal mask as well as a calibration procedure for determining the positive airway pressure. The Miles patent in no way remedies the deficiencies of either the Moa and Boussignac patents with regard to disclosing two independent Venturi devices each having a respective inlet, or that the tubing connecting between the source of high pressure air and the two inlets of the Venturi devices serves as the strapping means for strapping the nasal interface to the person's head for holding the nasal interface in place. Further, Miles does not discloses two independent Venturi devices that are mounted on opposite ends of a flat elongated flexible member configured to be placed above the upper lip of a person, as claimed with regard to independent claims 28 and 41. With regard to independent claim 28, the Miles patent also does not disclose a controller unit having a microprocessor and a memory device which in conjunction with a sensor allows for short term and long term regulation of the air flow delivered to the person in accordance with real-time respiratory cycles and the long term breathing pattern of the person.

Regarding the control unit, now incorporated into independent 28, the Office Action at page 19, states that "Miles discloses a control unit and monitoring system for determining CPAP pressure for apnea treatment". Further, the office action states that "[I]t would have been obvious to one having ordinary skill in the art to add sensors as taught by Miles to the CPAP delivery device in order to provide, controlled monitored method of delivering CPAP to a patient". Applicant respectively submits that the present

invention does not deliver CPAP (continuous constant positive airway pressure) for treating apnea but rather, it delivers a controllable variable positive pressure according to the real-time needs of the person suffering from sleep apnea.

Thus, the present invention provides for adjusting the flow of air in accordance to the respiratory cycles, by for example stopping the flow of air during exhalation phase, and further in accordance with the long-term monitored breathing pattern so as to turn off the supply of air when normal breathing is detected and turn it back on when irregular breathing is detected. It should be noted, that during sleep there are periods of normal breathing in which no external delivery of air is required to open the airways. In contradistinction, as the examiner's himself notes, Miles teaches a monitoring system for determining the CPAP pressure to be used for the treatment of apnea, and not a system for actually treating the apnea. In other words, Miles teaches a device to be used in a sleeping lab for performing automatic calibration of the optimum pressure suitable for CPAP treatment of a specific patient (col. 2, lines 50-60), the optimal pressure depending on the severity of the apnea in each individual. Thus, contrary to the examiner's argument, once the CPAP pressure is determined, for example by Miles' system, there is no reason or motivation to add sensors and/or control to a CPAP delivery device since the concept behind a CPAP is to provide a constant unvaried continuous positive pressure (as its name implies). Thus, Applicants respectfully submit that none of the cited references teaches a system for treating sleep apnea with a control unit, comprising a microprocessor and a memory device for monitoring breathing pattern, that enables short and long-term regulation of the flow of air delivered to the patient.

Claim 55 was rejected under U.S.C. § 103(a) as being unpatentable over Moa et al. in view of Boussignac and Sherrod and further in view of Hill.

Dependent claim 55 depends from independent claim 53, and provides that the source of compressed is an oil-less air compressor.

The Hill patent as discussed above, is offered for the purpose of teaching a portable oxygen concentrator system wherein the compressor is preferably an oil-less compressor to prevent the possibility of oil or grease from entering the air flow path. The Hill patent does not address the limitations addressed above with respect to the Boussignac patent or the Sherrod patent.

Reconsideration and withdrawal of the 35 U.S.C. 103(a) rejection is respectfully requested.

Applicant respectfully suggests that the innovation in this application, in contrast to the cited references, is a system and method especially designed for simple and seamless treatment of sleep apnea patients by the delivery of high-pressure air through flexible narrow tubing to a unique air delivery nasal interface and automatically regulating the high pressure entering the nasal interface by a control unit linked to a sensing system, able to instantaneously stop or resume the flow of air as well as regulate the pressure according to the person's needs.

Applicant believes that the application is now in order for allowance. Accordingly a notice of allowance for all the claims is respectfully requested.

Respectfully submitted,

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AMENDMENTS IN THE DRAWINGS

Attached please find replacement drawing sheets 2, 5 and 8 filed herewith in compliance with 37 CFR Sec. 1.84.

APPENDIX